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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/785,369 | 02/23/2004 | Min Wan | D 2003.784 US | 8537 |
| 27624 | 7590 | 01/05/2007 | EXAMINER | |
| AKZO NOBEL INC. INTELLECTUAL PROPERTY DEPARTMENT 120 WHITE PLAINS ROAD 3RD FLOOR TARRTOWN, NY 10591 | | | AUDET, MAURY A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/05/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

| | | |
|-----------------|--------------|--|
| Application No. | Applicant(s) | |
| 10/785,369 | WAN ET AL. | |
| Examiner | Art Unit | |
| Maury Audet | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02/23/2004.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3 and 6-18 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) 3 and 13-18 is/are allowed.
6) Claim(s) 1 and 6-12 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the species Glycine-Glycine and 25 mM, in the reply filed 10/11/06, is acknowledged. The traversal is on the ground(s) that a serious burden would not apply to a search of all dipeptides in the present invention, and that all can be searched and examined without imposing a serious burden on the Examiner. This is not found persuasive because a search each species is necessarily a distinct search, which may contain art does not anticipate or render obvious other species. In that respect an initial search, retrieval, and application of art over more than one species does constitute an undue search burden. However, commensurate with species practice, all species will ultimately be searched and examined should the elected species and the other species be found free of the art.

Claims 1, 3, 6-18 are pending and examined on the merits.

The requirement is still deemed proper and is therefore made FINAL.

However, the present action is made NON-FINAL, since the substance of the 35 USC 103 rejection has changed, upon reconsideration, and the previous indication of allowable subject matter vacated, in part.

Specification Observation

On specification page 10, para 2, the word “by” should be written --be--.

Appropriate correction is suggested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barri et al. (US 2003/0045004 A1).

As discussed previously, Barri et al. teach the use of monomeric amino acids (e.g. listing by example lysine, glycine, arginine) and other enzymatic or non-enzymatic inhibitors of carbamylation, to inhibit or delay carbamylation of proteins in a urea or cyanate containing solution (abstract, para's 12, 28, 39-40, and claims 7-9, 18-19).

[As to rejections of claim 12 above, it is noted that the compounds used in therein inherently possess a buffering capacity of about neutral, absent evidence to the contrary].

Barri et al. teach inhibiting and/or delaying carbamylation of peptides using compounds other than ethylene diamine like compound. However, Barri et al. does not expressly teach a process using the term “solubilizing” or “purifying” said peptide (claims 4-5); that the protein is to be ribonuclease or RNase A (claims 6-7); or that the carbamylation percent protection of about

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100% after three weeks, a compound concentration within the broad range of 1-150mM, or cyanate in the solution at a concentration of about 5mM (claims 8-9, and 11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use any of the mono amino acids of glyciamide, histidine, or 4-hydroxyl proline to inhibit or delay carbamylation of proteins in a urea or cyanate containing solution in Barri et al., because Barri et al. advantageously teach the use of any mono amino acid to carry out the same, which would include mono amino acids known to those of ordinary skill in the art, such as glyciamide, histidine, or 4-hydroxyl proline, and the selection thereof would have been merely a matter of routine optimization by one of ordinary skill in the art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to "solubilize" or "purify" the peptides being inhibited or delayed from carbamylation in any of the references above, because these "terms of art" are merely known objectives (solubilizing/purifying) to one of skill in the art in general peptide preparation, and more specifically are the desired end result beneficially taught by references, by using the underlying intermediate step of inhibiting or delaying carbamylation of peptides.

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply inhibiting or delaying carbamylation to the specific peptide/protein of ribonuclease/RNase A in any of the references above, because these are merely well known peptides in the art which the references' teachings were expected to be applied, like the peptides of example the references beneficially taught the inhibition or delaying of carbamylation therein.

If not inherently in the references, it would have been obvious to one of ordinary skill in the art at the time of the invention to arrive at a carbamylation percent protection of about 100%

after three weeks, a compound concentration within the broad range of 1-150mM, and cyanate in the solution at a concentration of about 5mM, in the references above, because the references all advantageously teach the use of like compounds to carry out the decarbamylation of peptides (the underlying process), and arriving at the above ranges to carry out the same process is merely a matter of routine optimization by one of ordinary skill in the art, depending on the desired effect.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

Claims 3 and 13-18 as drawn to a method for inhibiting and/or delaying carbamylation of a peptide in a urea or cyanate solution, using a dipeptide was not reasonably taught or suggested by the prior art of record. Namely, Barri et al. is the closest prior art, but is exclusively drawn to the use of mono amino acids, with no express teaching, suggestion, or reasonable motivation (that could be made based on the prior art currently of record) to advance the mono amino acids to dipeptides for the same purpose. As Barri et al.'s literature review indicates (para 9):

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"Very few studies have been aimed at the prevention of carbamylation, and all have involved lens [eye] protein. [] There are no studies in which any amino acid has been used to prevent carbamylation of proteins or lipids."

Claims 2-3, and 10, of claims 2 and 10, or dipeptides generally (claim 3); are not reasonably taught or suggested by the prior art of record.

Conclusion

Claims 3 and 13-18 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 12/22/06


Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600